UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Memorandum

Date: August 23, 2018

Subject: Maine WQS

To: Alexandra Dunn, EPA Region 1 Administrator

From: Michael Knapp, Office of Regional Counsel

Per your request at the meeting on Wednesday, I have enclosed a few record excerpts that you may find useful. The enclosed materials are:

- Excerpt from the response to comments (RTC) document for EPA's federal rule regarding treating the tribe as the "target population."
- Excerpt from the RTC regarding the comment received from the American Forest & Paper Association regarding "compounded conservatism."
- An internal analysis from the Office of Water responding in more detail to the "compounded conservatism" argument.

Ex. 5 DPP / ACP / AWP

that it had the authority to implement WQS in waters in Indian lands or that the state WQS were adequately protective of those waters.

One commenter argued that EPA's position that the Agency had not previously approved state WQS for waters in Indian lands is an "absurd position" because "it would result in a decades-long regulatory void based on a lack of any WQS and resulting CWA protections for all of Maine's Indian waters."[68] EPA agrees that its interpretation reflects a gap in WQS coverage in waters in Indian lands up to February 2015. EPA filled most of that gap with its five decisions approving many of Maine's WQS for waters in Indian lands in 2015 and 2016, and will fill the remaining gap, with the exception of HHC for arsenic, dioxin, and thallium, with this final rule. While EPA agrees that this situation is not desirable, EPA's interpretation is necessary to ensure that state WQS are applied to Indian waters only where the state has legal authority to do so and the state WQS are adequate under the CWA as applied in Indian waters. The interpretation that the state advocates would result in its WQS having been approved by EPA in tribal waters essentially inadvertently, without any conscious consideration on a reviewable record of the state's authority or the WQS effect on tribal uses. Moreover, there would have been no opportunity for the tribes to consult with EPA, consistent with the United States' government-to-government relationship with the tribes as reflected in, for example, Executive Order 13175 and EPA's Policy on Consultation and Coordination with Indian Tribes, about these questions that are central to their culture and status under the settlement acts.

The question of whether the state has jurisdiction to apply state WQS in tribal waters is not the focus of this action, but for the purposes of further explaining EPA's interpretation of its role in reviewing and approving or disapproving the state's WQS in tribal waters, the relationship between the state's jurisdictional authority under the settlement acts and this action is relevant. As further explained above and in EPA's February 2015 decision, under basic principles of federal Indian law and EPA policy, a state must expressly demonstrate its authority and the agency must make an express finding of the state's authority before state WQS can apply in tribal waters. This principle was a critical step in the analysis that allowed EPA to reconcile two potentially conflicting elements of the settlement ratified in MICSA. An important argument opposing the conclusion that the settlement acts authorize the state to set WQS in the tribes' waters was that this would give Maine unbridled authority to diminish or effectively repeal the provisions for sustenance fishing in the settlement acts. The assertion was that if the state could apply its WQS to tribal waters, it would conflict with the tribes' ability to practice sustenance fishing. EPA's review and assessment of how Maine's WQS affect tribal uses in Indian waters is an essential step in EPA's response to this argument. It is possible to reconcile the state's setting WQS in Indian waters with the tribes' ability to fish for their sustenance under the settlement acts because sustenance fishing is included in the fishing designated use that both the state and EPA are required to protect under the CWA. EPA's exercise of its oversight role and obligation to review state WQS before they apply in tribal waters effectively harmonizes the jurisdictional grant to the state in MICSA and the provision for tribes in Maine to sustain themselves on the land base that the Indian settlement acts established for the tribes.

3. Tribes as Target Population

EPA received two comments that it improperly and without justification identified the tribes as the target population, as opposed to a highly exposed subpopulation, for the HHC for waters in Indian lands. On the contrary, EPA's approach is entirely consistent with EPA regulations and policy, as informed by the settlement acts.

Pursuant to 40 CFR 131.11(a)(1), water quality criteria must be adequate to protect the designated uses. Developing HHC to protect the sustenance fishing designated use in waters in Indian lands necessarily

[67] *See* Comments of Maine's Attorney General, page 10.

involves identifying the population exercising that use as the target population.[69] The tribes are not a highly exposed or high-consuming subpopulation in their own lands; they are the general population for which the federal set-aside of these lands and their waters was designed.[70] Treating tribes as the target general population results in HHC sufficient under the CWA to ensure that the tribes' ability to exercise the designated use of sustenance fishing, as provided for in the settlement acts, is not substantially affected or impaired. Therefore, the tribal population must be the focus of the risk assessment supporting HHC for the waters to which the sustenance fishing use applies. To do otherwise risks undermining the purpose for which Congress established and confirmed the tribes' land base, as described more fully in Topic 3.1 above.

Contrary to the commenters' claims, EPA's 2000 Methodology does not mandate that the tribes be treated as a highly exposed subpopulation. EPA's general approach in the 2000 Methodology, and in deriving national CWA section 304(a) recommended criteria, is for HHC to provide a high level of protection for the general population, while recognizing that more highly exposed "subpopulations" may face greater levels of risk.[71] However, in addition to recommending protection of the general population based on fish consumption rates designed to represent "the general population of fish consumers," the 2000 Methodology recommends that states assess whether there might be more highly exposed subpopulations or "population groups" that require the use of a higher fish consumption rate to protect them as the "target population group(s)."[72] The 2000 Methodology does not speak to or expressly envision the unique situation of setting HHC for waters where there is a tribal sustenance fishing designated use. Nevertheless, it is entirely consistent with the 2000 Methodology for EPA to identify the tribes as the target general population for protection, rather than as a highly exposed subpopulation, and to apply the 2000 Methodology's recommendations on exposure for the general population, including the FCR and CRL, to the tribal target population.

One commenter disputed whether EPA has the authority under the CWA to second-guess the state's risk management decision, which it asserts protects the tribes to a level of risk equivalent to $1x10^{-5}$, even if one assumes they consume 286 g/day of fish. The commenter argues that this is a reasonable level of risk for the general population under EPA guidance. If the tribes are treated as a highly exposed subpopulation under the state's WQS, the commenter argues that they may consume up to 3240 g/day of fish with a $1x10^{-4}$ level of risk, consistent with EPA guidance. EPA disagrees. The flaw in this approach is that it ignores the purpose of the designated use of sustenance fishing in these waters and the reason Congress and the state agreed to identify these waters for the tribes to use in this manner. If high-end consumers are eating fish in a water with no sustenance fishing designation, they are highly exposed individuals fishing in waters that are designated for general recreational fishing. They are appropriately treated as part of a highly exposed subpopulation among the general population of recreational fishers for which that recreational fishing designation is designed. But where the waters are designated for sustenance fishing,

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[69] Maine's Attorney General concedes as much. Her objection to EPA's approach rests on her assertion that there is no designated use of sustenance fishing for the waters in Indian lands. But she recognizes that had the Maine Legislature adopted proposed legislation for a "subsistence fishing" designated use for a portion of the Penobscot River, the adoption of that use would have protected the subsistence fishers as the target population for the stretch of the river to which the use applied. *See* Comments of Maine's Attorney General, page 11.

[70] EPA recognizes that tribal members will not be the only population fishing from some of these waters. On major rivers such as the Penobscot River, for example, the general population has the right to pass through the waters in Indian lands. The presence of some nonmembers fishing on these waters, however, does not change the fact that the resident population in the Indian lands is made up of tribal members who expect to fish for their sustenance in the waters in Indian lands pursuant to the settlement acts.

[71] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). U.S. Environmental Protection Agency, Office of Science and Technology, Washington, DC. EPA 822-B-00-004, pp. 2-1 to 2-3.

[72] *Id.*, pp. 4-24 to 4-25.

and that designation stems from state and federal statutes that establish the sustenance fishing use to support a tribe's ability to continue its sustenance lifeways, the focus or purpose of the use is sustenance fishing by the tribes. They are the general population that the use is designed to protect. Having concluded that the tribes are the general population to be protected, EPA looked to state regulation to apply Maine's own risk management decision about how a general population should be protected, to a $1x10^{-6}$ level of risk, consistent with EPA's own guidance and general practice in promulgating federal criteria.

4. Use of Unsuppressed Data

EPA received several comments that the use of unsuppressed fish consumption data in determining the FCR is improper and neither authorized nor required under the CWA. EPA disagrees. CWA sections 101 and 303 and EPA's implementing regulations at 40 CFR part 131 provide the legal basis for EPA's use of unsuppressed fish consumption data in deriving the final HHC. CWA section 303(c)(2)(A) requires that water quality criteria be "based upon" applicable designated uses, and that such uses and criteria "shall be such as to protect the public health or welfare, enhance the quality of water and serve the purposes of this Act." The "purposes of this Act" are in CWA section 101, and include, among other things, "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters" and "water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water." EPA's implementing water quality regulations at 40 CFR § 131.11 require water quality criteria to be based on sound scientific rationale and sufficient to protect the designated use, regardless of whether that use is currently being met. A sustenance fishing designated use, by definition, represents a level of fish consumption that is adequate to provide sustenance, regardless of whether such consumption is occurring today. It is entirely consistent with the CWA and regulations for EPA to determine that to protect the designated use, it is necessary and appropriate to derive the HHC using a FCR that reflects a sustenance level of consumption that is not artificially suppressed as a result of concerns about pollution or fish contamination where such data are available.

EPA maintains that it is important, as a CWA goal, to avoid the suppression effect that may occur when criteria are derived using a FCR for a given target population (tribal or other) that reflects an artificially diminished level of fish consumption from an appropriate baseline level of consumption for that population.[73] As EPA stated in the preamble to the proposed rule, it is EPA's scientific and policy judgment that where sustenance fishing is a designated use of the waters (due to, for example, a tribal treaty right or other federal law that provides for a tribe to fish for its sustenance), selecting a FCR that reasonably represents current unsuppressed fish consumption based on the best available information is necessary and appropriate to ensure that such sustenance fishing use is protected.

To use a FCR that is suppressed would not result in criteria that actually protect a sustenance fishing use because it would merely reinforce the existing suppressed use, or worse, set in motion a downward spiral of further reduction/suppression of fish consumption due to concerns about the safety of available fish or depleted fisheries. The CWA is meant not merely to maintain the status quo, but to improve water body conditions and the health of those consuming fish from local waters in order to protect designated uses. Therefore, deriving criteria using an unsuppressed FCR furthers the restoration goals of the CWA (section 101, which is incorporated into section 303, as explained above) and ensures protection of human health-related designated uses (as pollutant levels decrease and fish consumption increases over time).

Any fish consumption rate used in setting criteria to protect a sustenance fishing use must allow for the

[73] USEPA. January 2013. *Human Health Ambient Water Quality Criteria and Fish Consumption Rates: Frequently Asked Questions* ("2013 FAQ"). Commenters claimed that EPA cited to the 2013 FAQ as the source of its authority to use unsuppressed fish consumption data, and objected that the 2013 FAQ had never been subjected to public notice and comment. However, as explained above, EPA's authority is anchored in the CWA and its implementing regulations, not the 2013 FAQ.

DEC. 2016 RESP. TO COMMENTS

Topic 5 Cancer Risk Level and Exposure Parameters Used in Derivation of the Human Health Criteria (Except for the Fish Consumption Rate)

EPA Summary of Comments and Response:

1. Cancer Risk Level

With respect to the cancer risk management value used in deriving the HHC of 10^{-6}, one commenter noted that this value was unduly protective of public health while another implied the Agency could adopt a more protective risk management level , and several supported EPA's use of 10^{-6}. Still other commenters noted that historically the waters of Maine and the fish that swam in them were at one time clean and free of all chemical pollutants and longed for the waterways of Maine to be restored to such pristine conditions. The Clean Water Act (CWA) provides EPA with the authority and the responsibility to restore and maintain the chemical, physical, and biological integrity of the Nation's waters but does not explicitly give the Agency authority or the responsibility to make the waters free of all pollutants. In promulgating HHC for the tribes in Maine, EPA incorporated an excess cancer risk level of 10^{-6} as the appropriate target level for two reasons. First, it is consistent with Maine DEP Rule 06-096, Chapter 584, which EPA approved for waters in Indian lands on February 2, 2015 and which specifies that water quality criteria for carcinogens must be based on a 10^{-6} CRL.[114] Second, it is consistent with EPA guidance that states, "For deriving CWA section 304(a) criteria or promulgating water quality criteria for states and tribes under Section 303(c) based on the 2000 Human Health Methodology, EPA intends to use the 10^{-6} risk level, which the Agency believes reflects an appropriate risk for the general population."[115] As explained above, EPA considers the tribes to be the general target population for waters in Indian lands. In promulgating HHC that correspond to an excess cancer risk level of 10^{-6} for tribes in Maine, not only is EPA acting consistent with both EPA guidance and Maine's existing rule, but EPA is providing the tribes engaged in sustenance fishing in waters in Indian lands with an equivalent level of cancer risk protection as is afforded to the general population in Maine outside of waters in Indian lands.

2. Compounded Conservatism

EPA received one comment claiming that the default values used to derive EPA's national HHC result in unnecessarily stringent criteria because of "compounded conservatism."[116] EPA disagrees with the comment. EPA selects a mixture of high-end and central (mean) tendency inputs to the equation used to derive HHC in order to derive recommended criteria that "afford an overall level of protection targeted at the high end of the general population (i.e., the target population or the criteria-basis population."[117] As an example, the default body weight (80 kg) used an arithmetic mean value for the US population. BAFs were computed using mean lipid values and median (i.e., 50th percentile) values for dissolved organic carbon and particulate organic carbon. Since EPA received and responded at length to comments received on the choice of default parameter values (e.g. drinking water intake rate, body weight) as part of the 2015 Human Health Ambient Water Quality Criteria: 2015 Update ("2015 Update"), EPA incorporates its

[114] The only exception from the requirement to use a CRL of 10^{-6} in Chapter 584 is for arsenic, for which a CRL of 10^{-4} is required. EPA disapproved the arsenic CRL for waters in Indian lands.
[115] United States Environmental Protection Agency (U.S. EPA). 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health.* EPA-822-B-00-004. Page 2-6.
[116] EPA understands "compounded conservatism" to describe the impact of using conservative, upper-bound estimates of input values to obtain a conservative estimate of risk modeled as a function of those input values.
[117] United States Environmental Protection Agency (U.S. EPA). 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health.* EPA-822-B-00-004. Page 2-1

responses to those comments on the 2015 Update.[118] EPA's 2000 Human Health Criteria Derivation Methodology describes EPA's approach for assigning input values for multiple parameters in section 4.3. Moreover, EPA notes that the State of Maine has also chosen to incorporate similarly identified default values recommended by EPA in the past when Maine developed its own HHC.[119]

3. Meaningful Protection

EPA received two comments that its HHC will not make a measurable or meaningful difference in the reduction of lifetime cancer rates for tribes in Maine in comparison with Maine's disapproved HHC. One commenter asserted that EPA's FCR of 286 g/day would only result in a theoretical decrease in the lifetime cancer risk for men from 0.420500 to 0.420491, and for women from 0.375800 to 0.375791, compared to use of Maine's FCR of 32.4 g/day. The other commenter urges the use of a 10^{-5} CRL rather than 10^{-6}, based on its analysis that, when added to the background risk of developing cancer of "about .40000," the theoretical excess lifetime cancer risk for criteria based on a CRL of 10^{-6} would be .400001 compared to .40001 for criteria based on 10^{-5}, a "non-measurable difference" according to the commenter.

The commenters' calculations purport to show that there is a "non-measurable difference" in cancer risk on top of the background level of cancer risk from increased stringency in human health criteria. In each case, the commenters use current lifetime risk of developing cancer of approximately 40% (42.0% for males and 37.6% for females), which can be found on the webpages of the American Cancer Society. However, this should not be used for the comparison because all it does is obscure the difference between two rates that represent fairly low cancer risk tolerance (1 in a million and 1 in 100 thousand), or between two fish consumption rates that are both calculated at a low cancer risk tolerance, by adding in the current relatively high actual lifetime cancer risk from all causes. It is not informative or surprising that a desirable cancer risk tolerance is well below today's incidence rate. The theoretical excess lifetime cancer risk difference is ten-fold when comparing a 1 in a million risk to a 1 in 100 thousand risk and up to nine-fold when comparing criteria based on consuming 286 g/day versus 32.4 g/day of fish. Human health criteria are designed for an individual's excess cancer risk using a predefined probability approach, widely accepted in environmental regulation, based on a person's chance of developing cancer above and beyond the chance of developing cancer from all other causes, over the course of an individual's lifetime.

4. Body Weight

The Penobscot Nation commented that EPA should use a 70 kg body weight in lieu of 80 kg, stating that 70 kg represented local data and citing an EPA RARE report[120] and the Penobscot Nation's Tribal Water Quality Standards as two sources for the local data. EPA agrees with the commenter that site-specific or local data relevant to the population of interest is preferable over default exposure values based on national surveys. However, the body weight used in the cited RARE report was based on EPA's pre-2015 default body weight as obtained from a national survey and not based on measured site-specific or local data. Furthermore, EPA's RARE Report specifically cited the use of 70 kg as an uncertainty of the analysis for an adult tribal member[121] and EPA found no indication that the Penobscot Nation's Tribal

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[118] The Response to Comments on the 2015 Update are available in the docket for this rulemaking and at: https://www.epa.gov/sites/production/files/2015-10/documents/epa-response-to-public-comments-to-human-health-final-criteria.pdf.

[119] *See, e.g.*, Letter from Brian Kavanah, Maine Bureau of Land and Water Quality, to Ellen Weitzler, USEPA, RE: Revisions to 06-096 CMR 584, *Surface Water Quality Criteria for Toxic Pollutants Protection of Sensitive Subpopulations* (Oct. 6, 2011).

[120] *The Penobscot River and Environmental Contaminants: Assessment of Tribal Exposure Through Sustenance Lifeways*, U.S. EPA Region 1, Final RARE Report, August 2015, Page 79. https://www.epa.gov/sites/production/files/2015-12/documents/final-rare-report-august-2015.pdf

[121] Id. at p.79

OFFICE OF WATER INTERNAL DOCUMENT

Ex. 5 DPP / ACP / AWP

Ex. 5 DPP / ACP / AWP

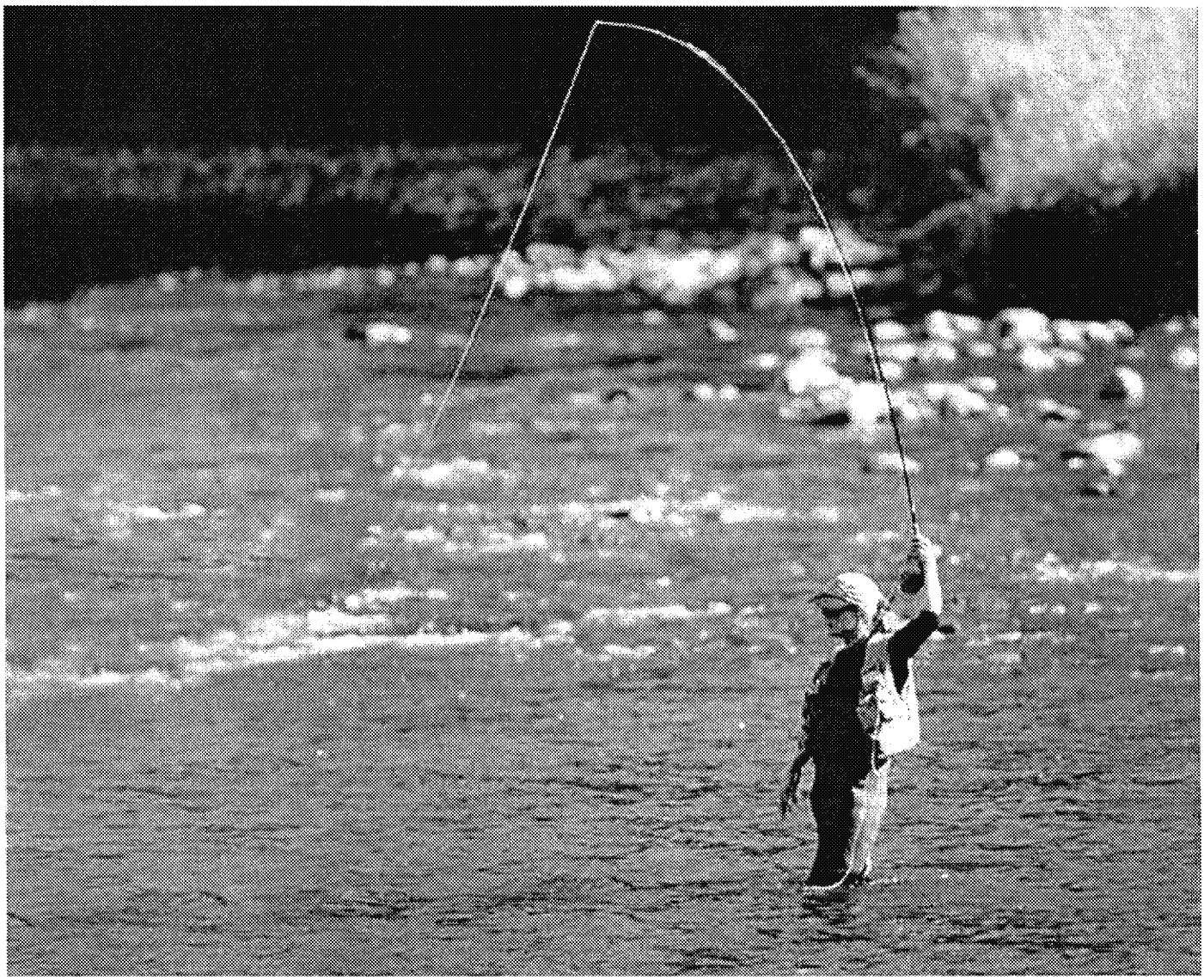
United States
Environmental Protection
Agency

Office of Water
Office of Science and Technology
4304

EPA-822-B-00-004
October 2000

EPA

Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)



USEPA (U.S. Environmental Protection Agency). 1999c. *Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. Peer Review Workshop Summary Report.* Office of Water. Washington, DC. EPA-822-R-99-015. September.

USEPA (U.S. Environmental Protection Agency). 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). Technical Support Document Volume 1: Risk Assessment.* Office of Science and Technology, Office of Water. Washington, DC. EPA-822-B-00-005. August.

3.2 NONCANCER EFFECTS

3.2.1 1980 AWQC National Guidelines for Noncancer Effects

In the 1980 AWQC National Guidelines, the Agency evaluated noncancer human health effects from exposure to chemical contaminants using Acceptable Daily Intake (ADI) levels. ADIs were calculated by dividing NOAELs by safety factors (SFs) to obtain estimates of doses of chemicals that would not be expected to cause adverse effects over a lifetime of exposure. In accordance with the National Research Council report of 1977 (NRC, 1977), EPA used SFs of 10, 100, or 1,000, depending on the quality and quantity of the overall database. In general, a factor of 10 was suggested when good-quality data identifying a NOAEL from human studies were available. A factor of 100 was suggested if no human data were available, but the database contained valid chronic animal data. For chemicals with no human data and scant animal data, a factor of 1,000 was recommended. Intermediate SFs could also be used for databases that fell between these categories.

AWQC were calculated using the ADI levels together with standard exposure assumptions about the rates of human ingestion of water and fish, and also accounting for intake from other sources (see Equation 1-1 in the Introduction). Surface water concentrations at or below the calculated criteria concentrations would be expected to result in human exposure levels at or below the ADI. Inherent in these calculations is the assumption that, generally, adverse effects from noncarcinogens exhibit a threshold.

3.2.2 Noncancer Risk Assessment Developments Since 1980

Since 1980, the risk assessment of noncarcinogenic chemicals has changed. To remove the value judgments implied by the words "acceptable" and "safety," the ADI and SF terms have been replaced with the terms RfD and UF/modifying factor (MF), respectively.

For the risk assessment of general systemic toxicity, the Agency currently uses the guidelines contained in the IRIS background document entitled *Reference Dose (RfD): Description and Use in Health Risk Assessments* (hereafter the "IRIS background document". That document defines an RfD as "an estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects over a lifetime" (USEPA,

1993a). The most common approach for deriving the RfD does not involve dose-response modeling. Instead, an RfD for a given chemical is usually derived by first identifying the NOAEL for the most sensitive known toxicity endpoint, that is, the toxic effect that occurs at the lowest dose. This effect is called the critical effect. Factors such as the study protocol, the species of experimental animal, the nature of the toxicity endpoint assessed and its relevance to human effects, the route of exposure, and exposure duration are critically evaluated in order to select the most appropriate NOAEL from among all available studies in the chemical's database. If no appropriate NOAEL can be identified from any study, then the LOAEL for the critical effect endpoint is used and an uncertainly factor for LOAEL-to-NOAEL extrapolation is applied. Using this approach, the RfD is equal to the NOAEL (or LOAEL) divided by the product of UFs and, occasionally, an MF:

$$\text{RfD (mg/kg/day)} = \frac{\text{NOAEL (or LOAEL)}}{\text{UF} \cdot \text{MF}} \qquad \text{(Equation 3-6)}$$

The definitions and guidance for use of the UFs and the MFs are provided in the IRIS background document and are repeated in Table 3-1.

The IRIS background document on the RfD (USEPA, 1993a) provides guidance for critically assessing noncarcinogenic effects of chemicals and for deriving the RfD. Another reference on this topic is Dourson (1994). Furthermore, the Agency has also published separate guidelines for assessing specific toxic endpoints, such as developmental toxicity (USEPA, 1991a), reproductive toxicity (USEPA, 1996a), and neurotoxicity risk assessment (USEPA, 1995). These endpoint-specific guidelines will be used for their respective areas in the hazard assessment step and will complement the overall toxicological assessment. It should be noted, however, that an RfD, derived using the most sensitive known endpoint, is considered protective against all noncarcinogenic effects.

TABLE 3-1. UNCERTAINTY FACTORS AND THE MODIFYING FACTOR

Uncertainty Factor	Definition
UF_H	Use a 1, 3, or 10-fold factor when extrapolating from valid data in studies using long-term exposure to average healthy humans. This factor is intended to account for the variation in sensitivity (intraspecies variation) among the members of the human population.
UF_A	Use an additional factor of 1, 3, or 10 when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. This factor is intended to account for the uncertainty involved in extrapolating from animal data to humans (interspecies variation).
UF_S	Use an additional factor of 1, 3, or 10 when extrapolating from less-than-chronic results on experimental animals when there are no useful long-term human data. This factor is intended to account for the uncertainty involved in extrapolating from less-than-chronic NOAELs to chronic NOAELs.
UF_L	Use an additional factor of 1, 3, or 10 when deriving an RfD from a LOAEL, instead of a NOAEL. This factor is intended to account for the uncertainty involved in extrapolating from LOAELs to NOAELs.
UF_D	Use an additional 3- or 10-fold factor when deriving an RfD from an "incomplete" database. This factor is meant to account for the inability of any single type of study to consider all toxic endpoints. The intermediate factor of 3 (approximately ½ $\log_{10}$ unit, i.e., the square root of 10) is often used when there is a single data gap exclusive of chronic data. It is often designated as UF_D.

Modifying Factor

Use professional judgment to determine the MF, which is an additional uncertainty factor that is greater than zero and less than or equal to 10. The magnitude of the MF depends upon the professional assessment of scientific uncertainties of the study and database not explicitly treated above (e.g., the number of species tested). The default value for the MF is 1.

Note: With each UF or MF assignment, it is recognized that professional scientific judgment must be used. The total product of the uncertainty factors and modifying factor should not exceed 3,000.

Similar to the procedure used in the 1980 AWQC National Guidelines, the revised method of deriving AWQC for noncarcinogens uses the RfD together with various assumptions concerning intake of the contaminant from both water and non-water sources of exposure. The objective of an AWQC for noncarcinogens is to ensure that human exposure to a substance related to its presence in surface water, combined with exposure from other sources, does not exceed the RfD. The algorithm for deriving AWQC for noncarcinogens using the RfD is presented as Equation 1-1 in the Introduction.

3.2.3 Issues and Recommendations Concerning the Derivation of AWQC for Noncarcinogens

During a review of the 1980 AWQC National Guidelines (USEPA, 1993b), the Agency identified several issues that must be resolved in order to develop a final revised methodology for deriving AWQC based on noncancer effects. These issues, as discussed below, mainly concern the derivation of the RfD as the basis for such an AWQC. Foremost among these issues is whether the Agency should revise the present method or adopt entirely new procedures that use quantitative dose-response modeling for the derivation of the RfD. Other issues include the following:

- Presenting the RfD as a single point value or as a range to reflect the inherent imprecision of the RfD;
- Selecting specific guidance documents for derivation of noncancer health effect levels;
- Considering severity of effect in the development of the RfD;
- Using less-than-90-day studies as the basis for RfDs;
- Integrating reproductive/developmental, immunotoxicity, and neurotoxicity data into the RfD calculation;
- Applying toxicokinetic data in risk assessments; and
- Considering the possibility that some noncarcinogenic effects do not exhibit a threshold.

3.2.3.1 Using the Current NOAEL/UF-Based RfD Approach or Adopting More Quantitative Approaches for Noncancer Risk Assessment

The current NOAEL/UF-based RfD methodology, or its predecessor ADI/SF methodology, have been used since 1980. This approach assumes that there is a threshold exposure below which adverse noncancer health effects are not expected to occur. Exposures above this threshold are believed to pose some risk to exposed individuals; however, the current approach does not address the nature and magnitude of the risk above the threshold level (i.e., the shape of the dose-response curve above the threshold). The NOAEL/UF-based RfD approach is intended primarily to ensure that the RfD value derived from the available data falls below the population effects threshold. However, the NOAEL/UF-based RfD procedure has

limitations. In particular, this method requires that one of the actual experimental doses used by the researchers in the critical study be selected as the NOAEL or LOAEL value. The determination that a dose is a NOAEL or LOAEL will depend on the biological endpoints used and the statistical significance of the data. Statistical significance will depend on the number and spacing of dose groups and the numbers of animals used in each dose group. Studies using a small number of animals can limit the ability to distinguish statistically significant differences among measurable responses seen in dose groups and control groups. Furthermore, the determination of the NOAEL or LOAEL also depends on the dose spacing of the study. Doses are often widely spaced, typically differing by factors of three to ten. A study can identify a NOAEL and a LOAEL from among the doses studied, but the "true" effects threshold cannot be determined from those results. The study size and dose spacing limitations also limit the ability to characterize the nature of the expected response to exposures between the observed NOAEL and LOAEL values.

The limitations of the NOAEL/UF approach have prompted development of alternative approaches that incorporate more quantitative dose-response information. The traditional NOAEL approach for noncancer risk assessment has often been a source of controversy and has been criticized in several ways. For example, experiments involving fewer animals tend to produce higher NOAELs and, as a consequence, may produce higher RfDs. Larger sample sizes, on the other hand, should provide greater experimental sensitivity and lower NOAELs. The focus of the NOAEL approach is only on the dose that is the NOAEL, and the NOAEL must be one of the experimental doses. It also ignores the shape of the dose-response curve. Thus, the slope of the dose-response plays little role in determining acceptable exposures for human beings. Therefore, in addition to the NOAEL/UF-based RfD approach described above, EPA will accept other approaches that incorporate more quantitative dose-response information in appropriate situations for the evaluation of noncancer effects and the derivation of RfDs. However, the Agency wishes to emphasize that it still believes the NOAEL/UF RfD methodology is valid and can continue to be used to develop RfDs.

Two alternative approaches that may have relevance in assisting in the derivation of the RfD for a chemical are the BMD and the categorical regression approaches. These alternative approaches may overcome some of the inherent limitations in the NOAEL/UF approach. For example, the BMD analyses for developmental effects show that NOAELs from studies correlate well with a 5 percent response level (Allen et al., 1994). The BMD and the categorical regression approaches usually have greater data requirements than the RfD approach. Thus, it is unlikely that any one approach will apply to every circumstance; in some cases, different approaches may be needed to accommodate the varying databases for the range of chemicals for which water quality criteria must be developed. Acceptable approaches will satisfy the following criteria: (1) meet the appropriate risk assessment goal; (2) adequately describe the toxicity database and its quality; (3) characterize the endpoints properly; (4) provide a measure of the quality of the "fit" of the model when a model is used for dose-response analysis; and (5) describe the key assumptions and uncertainties.